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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,518	02/12/2004	Edward Roydon Jost-Price	50164/033002	6397

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EXAMINER	
KIM, JENNIFER M	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,518	JOST-PRICE ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-61* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-29, and 57-60 to a composition and a kit comprising a non-steroidal immunophilin-dependent immunosuppressant (NSIDI) and an NsIDI enhancer (NsIDIE) in amount that together are sufficient in vivo to decrease proinflammatory cytokine secretion or production or to treat an immunoinflammatory disorder, classified in class 514, subclass 11.

II. Claims 30-55 drawn to a method of decreasing proinflammatory cytokine secretion or production and treating a patient diagnosed with or at risk of developing **rheumatoid arthritis** comprising administering to the patient and NsIDI and NsIDIE simultaneously or within 14 days of each other in amounts sufficient to treat said patient, classified in class 514, subclass 11.

III. Claims 30-55 drawn to a method of decreasing proinflammatory cytokine secretion or production and treating a patient diagnosed with or at risk of developing **Crohn's disease or ulcerative colitis** comprising administering to the patient and NsIDI and NsIDIE simultaneously or within 14 days of each other in amounts sufficient to treat said patient, classified in class 514, subclass 11.

IV. Claims 30-55 drawn to a method of decreasing proinflammatory cytokine secretion or production and treating a patient diagnosed with or at risk of developing **asthma or chronic obstructive pulmonary disease** comprising administering to the patient and NsIDI and NsIDIE simultaneously or within 14 days of each other in amounts sufficient to treat said patient, classified in class 514, subclass 11.

V. Claim 30-55 drawn to a method of decreasing proinflammatory cytokine secretion or production and treating a patient diagnosed with or at risk of developing **polymyalgia rheumatica** comprising administering to the patient and NsIDI and NsIDIE simultaneously or within 14 days of each other in amounts sufficient to treat said patient, classified in class 514, subclass 11.

VI. Claim 30-55 drawn to a method of decreasing proinflammatory cytokine secretion or production and treating a patient diagnosed with or at risk of developing **giant cell arteritis** comprising administering to the patient and NsIDI and NsIDIE simultaneously or within 14 days of each other in amounts sufficient to treat said patient, classified in class 514, subclass 11.

VII. Claim 30-55 drawn to a method of decreasing proinflammatory cytokine secretion or production and treating a patient diagnosed with or at risk of developing **systemic lupus erythematosus** comprising administering to the patient and NsIDI and NsIDIE simultaneously or within 14 days of

each other in amounts sufficient to treat said patient, class 514, subclass 11.

VIII. Claims 30-55 drawn to a method of decreasing proinflammatory cytokine secretion or production and treating a patient diagnosed with or at risk of developing **atopic dermatitis** comprising administering to the patient and NsIDI and NsIDIE simultaneously or within 14 days of each other in amounts sufficient to treat said patient, classified in class 514, subclass 11.

IX. Claims 30-55 drawn to a method of decreasing proinflammatory cytokine secretion or production and treating a patient diagnosed with or at risk of developing **multiple sclerosis** comprising administering to the patient and NsIDI and NsIDIE simultaneously or within 14 days of each other in amounts sufficient to treat said patient, classified in class 514, subclass 11.

X. Claims 30-55 drawn to a method of decreasing proinflammatory cytokine secretion or production and treating a patient diagnosed with or at risk of developing **myasthenia gravis** comprising administering to the patient and NsIDI and NsIDIE simultaneously or within 14 days of each other in amounts sufficient to treat said patient, classified in class 514, subclass 11.

XI. Claims 30-55 drawn to a method of decreasing proinflammatory cytokine secretion or production and treating a patient diagnosed with or at risk of

developing **psoriasis** comprising administering to the patient and NsIDI and NsIDIE simultaneously or within 14 days of each other in amounts sufficient to treat said patient, classified in class 514, subclass 11.

XII. Claims 30-55 drawn to a method of decreasing proinflammatory cytokine secretion or production and treating a patient diagnosed with or at risk of developing **ankylosing spondylitis** comprising administering to the patient and NsIDI and NsIDIE simultaneously or within 14 days of each other in amounts sufficient to treat said patient, classified in class 514, subclass 11.

XIII. Claims 30-55 drawn to a method of decreasing proinflammatory cytokine secretion or production and treating a patient diagnosed with or at risk of developing **psoriatic arthritis** comprising administering to the patient and NsIDI and NsIDIE simultaneously or within 14 days of each other in amounts sufficient to treat said patient, classified in class 514, subclass 11.

XIV. Claims 61 drawn to a method for identifiying combinations of compound useful for suppressing the secretion of proinflammatory cytokines in a patient in need of such treatment, said method comprising the steps set forth in claim 61, classified in class 514, subclass 11.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Groups II-XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be

shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product since the product can be used to treat aqueous deficient dry eyes.

Inventions II - XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different operations and effects because each of the medical disorder to be treated has different etiology and different known treatment.

Inventions Groups I-XIII and Group XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different operations and effects because Group XIV is related to method for identifying compounds while Groups II-XIII are related to a treatment of a medical disorders and Group I is related to a composition. It is noted that a method for identifying compounds is completely different than the treatment of a medical disorder or a composition as each of these group have different unrelated operations and effects.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their

recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicants are advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicants traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election of Species

If Applicants elect a single Group from Groups I-XIII, following election of species is required:

This application contains claims directed to the following patentably distinct species

A) a non-steroidal immunophilin-dependent immunosuppressant (NsIDI) set forth in claims 3, 5 and 33.

B) a NsIDI enhancer (NsIDIE) set forth in claims 7-14, 34-40

C) a further comprising agent set forth in claims 15-27 and 41-52.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, a non-steroidal immunophilin-dependent immunosuppressant (NsIDI) , a NsIDI enhancer (NsIDIE) and a further comprising agent are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicants are advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An

argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicants traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claims will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claims will not be rejoined. See MPEP 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Patent Examiner
Art Unit 1617

Jmk
June 13, 2007